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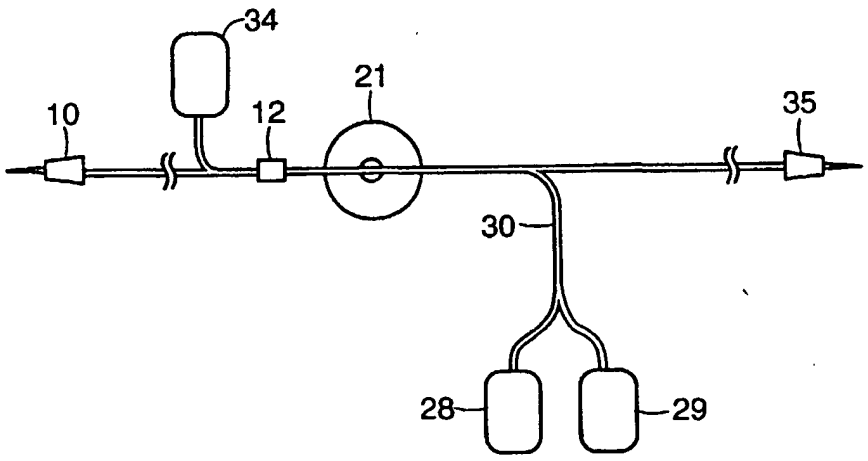
(54) Title: SYSTEM AND METHOD FOR PROCESSING BLOOD

(57) Abstract

A system for processing blood that is simple to implement and that reduces the need for human intervention. The system may be used to collect red blood cells. For such a system, a disposable set may be provided with an inlet port, an RBC container, a centrifuge rotor having a variable total volume, and a WBC filter, along with tubing connecting the port, the container, the rotor and the filter. The filter is located in tubing between the inlet port and the rotor, so that white blood cells are filtered from the blood before it reaches the rotor. A control unit is also provided and includes a spinner in which the rotor may be held, a flow-control arrangement for controlling flow among the various components of the disposable set, and an electronic controller. The whole blood is directed by the flow-control arrangement from the inlet through the filter to the rotor. The rotor includes an elastic diaphragm, and the control unit's flow-control arrangement includes a pump or other device for applying a positive and negative pressure to the rotor's elastic diaphragm. The spinner rotates the rotor so as to separate the whole blood into plasma and RBCs. Preferably, the plasma, is urged out of the rotor first and returned to the donor, while the rotor is still being spun. After the plasma has been removed from the rotor, the RBCs are urged from the rotor to an RBC container.



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SYSTEM AND METHOD FOR PROCESSING BLOOD

Technical Field

This invention generally relates to systems and methods for processing blood and other biological fluids.

Summary of the Invention

The present invention is directed to systems and methods for collecting a separated blood component that is free of white blood cells (WBCs), and in particular, systems and methods that are simple to use and that reduce the need for human intervention. A disposable set is provided with (i) a port (e.g., a cannula inserted into a vein of the donor) for permitting whole blood to flow from a donor into the disposable set, (ii) a WBC filter, (iii) a separation container wherein the whole blood is separated into components (for example, a centrifuge rotor or other separation means), (iv) a blood-component container for storing a separated blood component, and (v) tubing connecting the port, the filter, the separation container and the blood-component container. The port acts as an inlet allowing whole blood to flow into the disposable set. The WBC filter is located between the port (i.e., the inlet) and the separation container and is capable of filtering white blood cells from the whole blood. The inlet port is connected to the donor, and whole blood is drawn from the donor through the port. The whole blood is directed from the port through the WBC filter to the separation container, so that white blood cells are filtered from the whole blood before entering the separation container. After the whole blood is separated into a first component and a second component, one of the first and second components is directed from the separation container to the blood-component container.

A preferred embodiment of the present invention is directed to systems and methods for collecting red blood cells from a donor while returning plasma to the donor. Whole blood is removed from a donor, white blood cells (WBCs)

are filtered from the whole blood, and the filtered blood is directed to a centrifuge rotor, where the blood is separated into red blood cells (RBCs) and plasma. The plasma may be returned to the donor during the same procedure in which whole blood is drawn from the donor. At one or more times during the collection process, when all the rotor has been emptied of plasma, the red blood cells are urged from the rotor and collected in one or more RBC containers.

In a preferred embodiment, the system for collecting red blood cells includes a disposable set as set forth above, and having a centrifuge rotor for the separation container and an RBC container for the blood-component container. In preferred embodiments, the port also acts as an outlet, so as to permit the return of a separated blood component to the donor; alternatively, a separate outlet port may be provided. The WBC filter is located between the port and the centrifuge rotor. The RBC container is connected to a branch of the tubing leading from the rotor.

Preferably, the centrifuge rotor has a variable total volume. The rotor preferably includes a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions, wherein the tubing is connected to the rotor's fixed portion. In order to create a variable total volume, the centrifuge rotor may include in its rotatable portion an elastic diaphragm, which stretches to increase the total volume of the rotor. In such an embodiment, an internal wall is preferably included, for separating the diaphragm from the rotor's fixed portion.

The system also includes a control unit having a spinner in which the rotor may be held. The control unit may include means for varying the volume of the centrifuge rotor by changing the pressure of a gas adjacent the elastic diaphragm. Preferably, a vacuum may be applied to the elastic diaphragm by the control unit, so as to draw blood into the rotor.

In a preferred method of carrying out the invention, the rotor is placed in the spinner, and the port is connected to the donor. After the rotor is placed in the spinner, whole blood may be drawn from the donor through the port. The

whole blood is directed from the port through the WBC filter to the rotor, so that white blood cells are filtered from the whole blood. While the donor is still connected to the port, the spinner rotates the rotor so as to separate the whole blood into plasma and red blood cells. The plasma is urged out of the rotor first, while the rotor is still spinning, to be directed back to the donor. The second component is directed from the rotor to the RBC container.

In one embodiment, an inlet port may be used for drawing whole blood, and a separate outlet port may be used for returning the plasma component. In a preferred embodiment, a port is used to draw whole blood and to return the plasma component; in this embodiment, a temporary storage container is used to hold the plasma while whole blood is being collected, and the plasma is returned when the red blood cells are being processed by and urged from the rotor.

Brief Description of the Drawings

FIG. 1 shows a system according to the present invention.

FIG. 2 shows a sectional view of a rotor that may be used in the system of the present invention.

FIG. 3 shows a disposable set that may be used in the system shown in FIG. 1.

FIG. 4 shows an alternative disposable set.

FIG. 5 shows the arrangement of steps in a cycle of a process for collecting red blood cells using the disposable set of FIG. 4.

Description of Specific Embodiments

FIG. 1 shows an embodiment of a system according to the present invention. The system uses many of the components and features described in U.S. Patent Nos. 5,733,253 issued March 31, 1998 to Headley and Powers, and 5,651,766 issued July 29, 1997 to Kingsley, Headley and Halpern. Both of these patents are incorporated herein by reference.

The system includes a disposable set (such as the one shown in FIG. 3)

and a control unit that controls the disposable set. The disposable set includes an inlet port **10**, e.g., a cannula, which may act as a connector for attachment to a shunt or other arrangement for permitting whole blood to enter the disposable set from the donor. Tubing connects the various components of the disposable set. The whole blood passes through some of the tubing and flows into the centrifuge rotor **21** mounted in a control unit **20**. A WBC filter **12** is located in the tubing between the inlet port **10** and the rotor **21**. This filter **12** filters white blood cells from the whole blood. Filtering the whole blood before separation is easier than filtering the red blood cells after separation, because of the lower density of the whole blood. Filtering the whole blood before separation results in the white blood cells being removed from the plasma as well as the red blood cells.

The filtered blood is spun in the rotor at a sufficiently high speed so as to cause the blood to separate into plasma and red blood cells. The plasma is returned to the donor through an outlet port **35** (e.g., a cannula), while blood is being drawn from the donor. The red blood cells are collected in one or more RBC containers **28, 29**.

An anticoagulant bag **34** is preferably connected to the tubing between the inlet port **10** and the filter **12**, so as to provide anticoagulant to the whole blood being drawn. A metering valve **23** on and controlled by the control unit may be used to meter the anticoagulant from the anticoagulant container **34** into the whole blood being drawn from the inlet port **10**. In lieu of or in addition to valve **23**, a peristaltic pump or other flow-inducing arrangement may be used to add the anticoagulant to the whole blood and/or help draw blood from the donor. In a preferred embodiment, the tubing may be modified so that the anticoagulant is added to the whole blood coming from the donor at a point in the tubing much closer to the inlet port **10**. (In addition to--or in lieu of--the anticoagulant, a replacement fluid, such as saline, may be added to the whole blood being drawn. After the whole blood has been centrifuged, plasma is returned to the donor along with the replacement fluid. The replacement fluid provides the donor with a volume of fluid to replace the volume of red blood

cells that are collected. Adding replacement fluid to the whole blood has an anticoagulating effect. Anticoagulant may be added to the replacement fluid to provide more anticoagulation.)

The rotor **21** preferably has a variable total volume and two ports to permit the introduction of blood into the rotor at the same time a blood component is being removed. In a preferred embodiment, the rotor is of the type shown in Figures 10-15 or Figures 23-27 in above-referenced U.S. Patent No. 5,733,253.

FIG. 2 is a sectional view of a rotor which may be used in the system shown in FIG. 1, and which is a variation on the rotor shown in Figures 10-15 of U.S. Patent No. 5,733,253. The rotor includes a fixed portion **51**, which does not rotate and which (as shown in FIG. 1) is held in place by a brace **19** on the control unit **20**; a rotatable portion **52**, which is held and spun by a chuck in the control unit; and a rotary seal **53**, which maintains a seal between the fixed portion and the rotatable portion. The rotary seal preferably works in the same manner as the rotary seal shown in Figures 38 and 39 of U.S. Patent No. 5,733,253: The sealing force applied by the rotary seal **53** is not substantially affected by changes in air pressure within the rotor. The rotary seal is mounted on a base, which may be part of the rotor's fixed portion **51**. The rotary seal **53** includes first and second rigid seal members, which surround the axis of rotation, and which spin in relation to each other. As set forth in Patent No. 5,733,253, the first rigid seal member and the base define an annular passage between them, and the first rigid seal member has a step portion which extends radially across the annular passage. A spring member surrounds the rotary seal's axis of rotation and is connected to the base and to the first rigid seal member, so that the spring member applies a force pressing the first rigid seal member against the second rigid seal member. A flexible seal member surrounds the axis of rotation and prevents fluid flow between the first rigid seal member and the base. The flexible seal member extends across the annular passage such that pressure from the annular passage exerts forces on the flexible seal member and the step portion which cancel each other, so that the force with

which the spring member presses the first rigid seal member against the second rigid seal member is not substantially affected by pressure within the annular passage.

The rotor's fixed portion includes a rotor inlet 54 and a rotor outlet 55, which are connected by tubing with the rest of the disposable set. The tubing of the disposable set has a portion that provides whole blood to the inlet 54 of the rotor 21 and another portion that provides blood components from the rotor's outlet 55 to outlet port 35 and to the RBC-collection containers 28, 29. The rotor inlet 54 leads to a fluid passage down the fixed portion 51 to a pair of channels 56, which are in the rotor's rotatable portion 52. The channels 56 permit the blood that has come from the donor and passed through the WBC filter to flow to the outer perimeter of the rotor's interior volume. Because the rotor's interior volume is defined in part by a flexible, preferably elastic, diaphragm, the rotor has a variable total volume.

Preferably, only two such inflow channels 56 providing fluid communication from the rotor inlet 53 are used, in order to minimize the amount of blood trapped in the rotor when the process is completed, and these two channels are preferably disposed 180° from each other, in order to maintain balance in the rotor. In alternative embodiments, one or more than two inflow channels 56 may be used. The rotor includes an interior wall 58, which together with the flexible diaphragm 57 fully define the rotor's processing chamber. The interior wall 58 includes grooves on its bottom surface (not shown), which permit flow of blood components out of the rotor's processing chamber. In a preferred embodiment, the interior wall 58 includes two of these outflow grooves arranged 180° to each other and at 90° to the inflow channels 56. The outflow grooves lead to holes which pass up through the interior wall 58 to the region adjacent a collector 59. These holes (not shown) provide fluid communication between the outflow grooves and the collector 59, which is part of the rotor's fixed portion 51. The collector 59 collects the blood components flowing out of the processing chamber and directs the blood components up through a vertical passage to the rotor outlet 55.

Blood may be drawn into the rotor 21 by creating a vacuum in the chuck that holds the rotor 21. Alternatively, a peristaltic pump or other flow-inducing arrangement may be used, in lieu of or in addition to valve 23, to draw the whole blood from the port 10 into the rotor 21.

When a sufficient amount of whole blood has entered the rotor 21, the rotor is spun sufficiently fast so as to separate the blood into plasma and red blood cell components. After the blood has separated into plasma and red blood cells, valve 36 is opened, and plasma (and replacement fluid) is urged from the rotor 21 and is directed back to the donor through the outlet port 35. Plasma may be removed from the rotor as filtered blood is continuing to be introduced into the rotor.

Because the plasma component of the blood is being returned to the donor, two units of red blood cells may ordinarily be collected from the donor. In accordance with industry practice, the two units of red blood cells may be stored in two separate containers 28 and 29. In an alternative embodiment, a single container may be used, instead of two containers.

When it is determined that enough red blood cells have been collected, or when the rotor is substantially filled with red blood cells, whatever plasma remains in the rotor is forced from the rotor 21. When substantially all of the plasma has been removed from the rotor, valve 36 is closed and valves 27 and 25 are opened; the red blood cells are urged from the rotor and directed through valves 27 and 25 into the RBC-storage container 28. Since the white blood cells have already been filtered from the whole blood by the WBC filter 12, it is unnecessary in the present system to include a WBC filter between the rotor 21 and the RBC-storage containers 28 and 29.

The RBC-storage containers 28 and 29 are preferably bags and preferably contain RBC preservative (or storage solution). The RBC-storage bags 28 and 29 preferably hold a unit of red blood cells each. When a unit of red blood cells have been delivered to RBC-storage container 28, valve 25 is closed and valve 26 opened, thereby permitting the red blood cells to flow into RBC-storage bag 29. Valves 25, 26, 27 and 36, along with valve 23, are controlled by the control unit

20. (This method and system may be modified so that platelets are separately collected in the manner set forth in concurrently filed application serial no. __/_____, for a "System and Method for Collecting Platelets and Other Blood Components," bearing attorney docket no. 1611/117 and listing Thomas D. Headley as an inventor. This concurrently filed application is incorporated herein by reference.)

Depending on the maximum volume of the centrifuge rotor **21** used in relation to the total volume of the two RBC-storage containers **28, 29** used, it may be necessary to go through several cycles of filling the rotor, separating the blood into RBC and plasma components and urging plasma from the rotor until the rotor becomes filled with red blood cells, and at that point, urging the red blood cells from the rotor into one or more of the RBC-storage containers, in order to obtain desired amount (preferably two units) of red blood cells. Once the storage bags **28, 29** are filled with red blood cells, the storage bags are removed from the rest of the disposable set by cutting and heat sealing the tubes leading to the storage bags.

The process described hereinabove is highly automated compared to the prior-art methods of processing blood. A blood-donation technician installs the disposable set into the control unit **20** and inserts the inlet and outlet ports **10, 35** into the donor's arms. The technician, of course, also removes the cannulas from the donor's arms, and cuts and heat seals the tubing leading to the storage bags. The remaining steps of the process may be performed by the control unit: controlling the valves (and any pumps) to direct the flow of blood or blood components; determining when the rotor is sufficiently full; spinning the rotor; urging blood components from the rotor; and determining when the rotor has been emptied of a blood component.

As noted above, in a preferred embodiment of the control unit, each of valves **23, 25, 26, 27** and **36** are controlled by the control unit **20**, as is the speed that the rotor **21** is spun. Several of the valves **23, 25, 26, 27** and **36** may be combined into a single valve mechanism. The preferred embodiment of the rotor **21** has a stretchable elastic diaphragm **57** that defines the interior volume

of the rotor 21. As discussed in the above-referenced U.S. Patent Nos. 5,733,253 and 5,651,766, the elastic diaphragm (item 57 of FIG. 2) permits the total volume of the rotor 21 to be varied by varying the air pressure applied to the elastic diaphragm; this air pressure is also preferably controlled by the control unit so as to vary and control the total volume of the rotor 21. This air pressure may also be used to force fluid from the rotor 21 by increasing the air pressure sufficiently or to draw fluid into the rotor 21 by decreasing air pressure sufficiently.

The disposable set shown in FIGS. 1 and 3, as well as the control unit 20 shown in FIG. 1, may in a preferred embodiment be modified to use a single cannula or port to draw whole blood from the donor and return plasma to the donor. Such a disposable set is shown in FIG. 4. A temporary storage container 60 holds the separated plasma component for return to the donor. The separated plasma component is urged by the control unit from the rotor 21 through a portion 62 of the tubing to the temporary storage container 60. The control unit preferably urges the plasma from the rotor by increasing the gas pressure against the rotor's elastic membrane. Once plasma begins flowing from the rotor, the continued introduction of whole blood to the rotor tends to continue forcing separated plasma out of the rotor. After a desired amount of whole blood has been collected from the donor through port 10 (preferably when the rotor is almost full of red blood cells), the collection of whole blood is suspended, and plasma may be urged from the temporary storage container 60 through another portion 64 of the tubing to the port 10 and the donor. The control unit may be provided with means, such as a peristaltic pump working on tubing portion 64, for effecting and controlling the flow of plasma from the temporary storage container 60 to the port 10. The rest of the disposable set may be same as the disposable set shown in FIG. 3, including a WBC filter 17 in another portion of the tubing leading from the port 10 to the rotor 21, so as to permit the white blood cells to be filtered from the whole blood before it is separated; an anticoagulant container 34 may be attached to this same portion of the tubing. In a preferred embodiment, the anticoagulant container may be

connected to a point in the tubing closer to the port **10**, so as to introduce the anticoagulant to the whole blood as soon as possible after it is drawn from the donor.

The process of collecting red blood cells using the disposable set shown in FIG. 4 may involve several cycles of collecting whole blood from the donor and returning the separated plasma component to the donor. FIG. 5 shows an outline of steps in one such cycle. Each cycle is divided up into two periods: a first period **71** in which whole blood is drawn from the donor, i.e., a draw period (which in one embodiment lasts between 105 and 235 seconds), and a second period **72** in which plasma is returned to the donor, i.e., a return period (which lasts between 196 and 288 seconds). During the draw period **71**, the rotor--item **21** in FIG. 4--is filled with whole blood from the donor (step **73**), and the rotor is spun to separate the blood into plasma and RBC components. Plasma is urged from the rotor to the temporary container **60** (step **74**--of course, some of these steps may overlap). In an optional step (step **75**), the platelets may be separately collected in the manner set forth in concurrently filed application serial no. __/_____, for a "System and Method for Collecting Platelets and Other Blood Components," bearing attorney docket no. 1611/117 and listing Thomas D. Headley as an inventor. (As set forth previously, this concurrently filed application is incorporated herein by reference.) During the return period **72**, the red blood cells are concentrated, by increasing the rotational speed of the centrifuging rotor (step **76**), and the remaining plasma is removed from the rotor **21** to the temporary container **60** (step **77**). An RBC-storage solution may be added to the red blood cells, diluting the red blood cells (step **78**). In the final step of the cycle (step **79**), the red blood cells are directed through the portion **30** of the tubing to one of the two storage containers **28** or **29**.

When the red blood cells have been moved from the rotor to the storage containers, and when the plasma in the temporary container has been returned to the donor, the cycle may start again with the draw period **71** and the rotor filling step **73**. In one embodiment, the total cycle time lasts from 5 to 8.7

minutes (assuming a hematocrit range of 40 to 55 and a draw speed range of 60 to 100 ml/min). Four cycles may be executed, for a total procedure time of 20 to 34.8 minutes.

The disposable sets shown in FIGS. 3 and 4--the storage bags **28, 29,** filter **12,** centrifuge rotor **21** and the tubing--may be configured in several ways. The tubing may consist solely of tubes which may be squeezed by the control unit to direct flow or to pump in a peristaltic manner. Alternatively, the tubing may contain special valving or pumping components (such as a pumping/valving cassette) which may be acted on by the control unit. The phrase "flow-control arrangement" refers herein to any structure or system for controlling or causing flow of fluid between the various components of the systems of the present invention.

The control unit shown in FIG. 1 and the disposable set shown in FIGS. 1 and 3 may also be modified, by substituting a plasma collection container for the outlet port **35,** to permit the collection of plasma that is free of white blood cells, as well as the collection of red blood cells that are free of white blood cells.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A method of collecting a separated blood component that is free of white blood cells, the method comprising:

providing a disposable set having (i) a port for permitting whole blood to flow from a donor into the disposable set, (ii) a WBC filter, (iii) a separation container wherein the whole blood is separated into components, (iv) a blood-component container for storing a separated blood component, and (v) tubing connecting the port, the filter, the separation container and the blood-component container, wherein the filter is located between the port and the separation container and is capable of filtering white blood cells;

connecting the port to the donor;

drawing whole blood from the donor through the port;

directing the whole blood from the port through the filter to the separation container, so that white blood cells are filtered from the whole blood before entering the separation container;

separating the whole blood into a first component and a second component; and

directing one of the first and second components from the separation container to the blood-component container.

2. The method according to claim 1, wherein the separation container is a centrifuge.

3. The method according to claim 2, wherein the centrifuge rotor has a variable total volume.

4. The method according to claim 3, wherein the centrifuge rotor is provided with a fixed portion, a rotatable portion and a rotary seal providing a

seal between the fixed and rotatable portions, and the tubing is connected to the rotor's fixed portion.

5. The method according to claim 4, wherein the centrifuge rotor includes in its rotatable portion an elastic diaphragm, which stretches to increase the total volume of the rotor, and an internal wall, which separates the diaphragm from the rotor's fixed portion.

6. A method of collecting red blood cells, the method comprising:

providing a disposable set having a port, a filter, a centrifuge rotor, an RBC container, and tubing connecting the port, the filter, the rotor and the RBC container, wherein the filter is located between the port and the centrifuge rotor, and is capable of filtering white blood cells;

providing a control unit having a spinner in which the rotor may be spun;

placing the rotor in the spinner;

connecting the port to the donor;

after placing the rotor in the spinner, drawing whole blood from the donor through the port;

directing the whole blood from the port through the filter to the rotor, so that white blood cells are filtered from the whole blood before entering the rotor;

causing the spinner to rotate the rotor so as to separate the whole blood into a first component and a second component, wherein the first component is primarily plasma, and wherein the second component is primarily red blood cells;

urging the first component out of the rotor, while the rotor is still spinning; and

directing the second component from the rotor to the RBC container.

7. The method of claim 6, wherein the rotor is spun to separate the blood

components, while the donor is still connected to the port, and further including returning the first component to the donor.

8. The method according to claim 6, wherein the centrifuge rotor has a variable total volume.

9. The method according to claim 8, wherein the centrifuge rotor includes an elastic diaphragm, which stretches to increase the total volume of the rotor.

10. The method according to claim 9, wherein the control unit varies the volume of the centrifuge rotor by changing the pressure of a gas adjacent the elastic diaphragm.

11. A disposable set for use in a control unit for processing blood, the disposable set comprising:

a port;

a filter;

a separation container;

a blood-component container; and

tubing connecting the port, the filter, the separation container and the blood-component container;

wherein the filter is located between the port and the separation container, and is capable of filtering white blood cells from whole blood before separation.

12. A disposable set according to claim 11, wherein the separation container is a variable-volume centrifuge rotor having a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions.

13. A disposable set for use in a control unit for collecting red blood cells, the disposable set comprising:

a port;

a filter;

a centrifuge rotor;

an RBC container;

a temporary storage container; and

tubing connecting the port, the filter, the rotor, the container and the temporary storage container;

wherein the filter is located between the port and the centrifuge rotor, and is capable of filtering white blood cells, wherein the centrifuge rotor has a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions, and wherein the centrifuge rotor has a variable total volume.

14. The disposable set of claim 13, wherein the RBC container is connected to a branch of the tubing between the rotor and the temporary storage container.

15. The disposable set according to claim 13, wherein the centrifuge rotor is provided with a flexible diaphragm which defines the volume of the rotor.

16. A system for processing blood, the system comprising:

a disposable set having

a port for permitting the introduction of blood from the donor into the disposable set,

a separation container wherein the whole blood is separated into components,

a filter that is located in a fluid path between the port and rotor and that filters white blood cells from whole blood passing through the filter, wherein the filter is located between the port and the separation container, and is capable of filtering white blood cells, and

a blood-component container for storing a separated blood component, the blood-component container being in fluid

communication with the separation container; and

a control unit having a flow-control arrangement which urges a blood component from the separation container to the blood-component container after the blood has been separated.

17. The system according to claim 16, wherein the separation container is a variable-volume centrifuge rotor, and the control unit further includes means for spinning the rotor and for varying the volume of the rotor.

18. The system according to claim 17, wherein the centrifuge rotor includes an elastic diaphragm which defines the volume of the rotor, and wherein the control unit includes means for varying gas pressure adjacent the elastic diaphragm.

19. The system according to claim 18, wherein the means for varying gas pressure includes means for applying a vacuum to the elastic diaphragm, so as to draw blood into the rotor.

20. A system for collecting red blood cells from a donor, the system comprising:

a disposable set having

a port for permitting the introduction of blood from the donor into the disposable set;

a centrifuge rotor having a variable total volume;

a filter that is located in a fluid path between the port and rotor and that filters white blood cells from whole blood passing through the filter;

return means for permitting return of plasma to the donor, the return means being in fluid communication with the centrifuge rotor; and

an RBC container in fluid communication with the centrifuge rotor; and

a control unit having

a spinner that holds the rotor, the spinner being able to spin the rotor so as to separate blood into blood components; and

a flow-control arrangement which urges a blood component from the rotor while the rotor is being spun.

21. A system according to claim 20, wherein the return means includes a temporary storage container.

22. The system according to claim 20, wherein the control unit further includes means for varying the volume of the rotor.

23. The system according to claim 22, wherein the centrifuge rotor includes an elastic diaphragm which defines the volume of the rotor, and wherein the control unit includes means for varying gas pressure adjacent the elastic diaphragm.

24. The system according to claim 23, wherein the means for varying gas pressure includes means for applying a vacuum to the elastic diaphragm, so as to draw blood into the rotor.

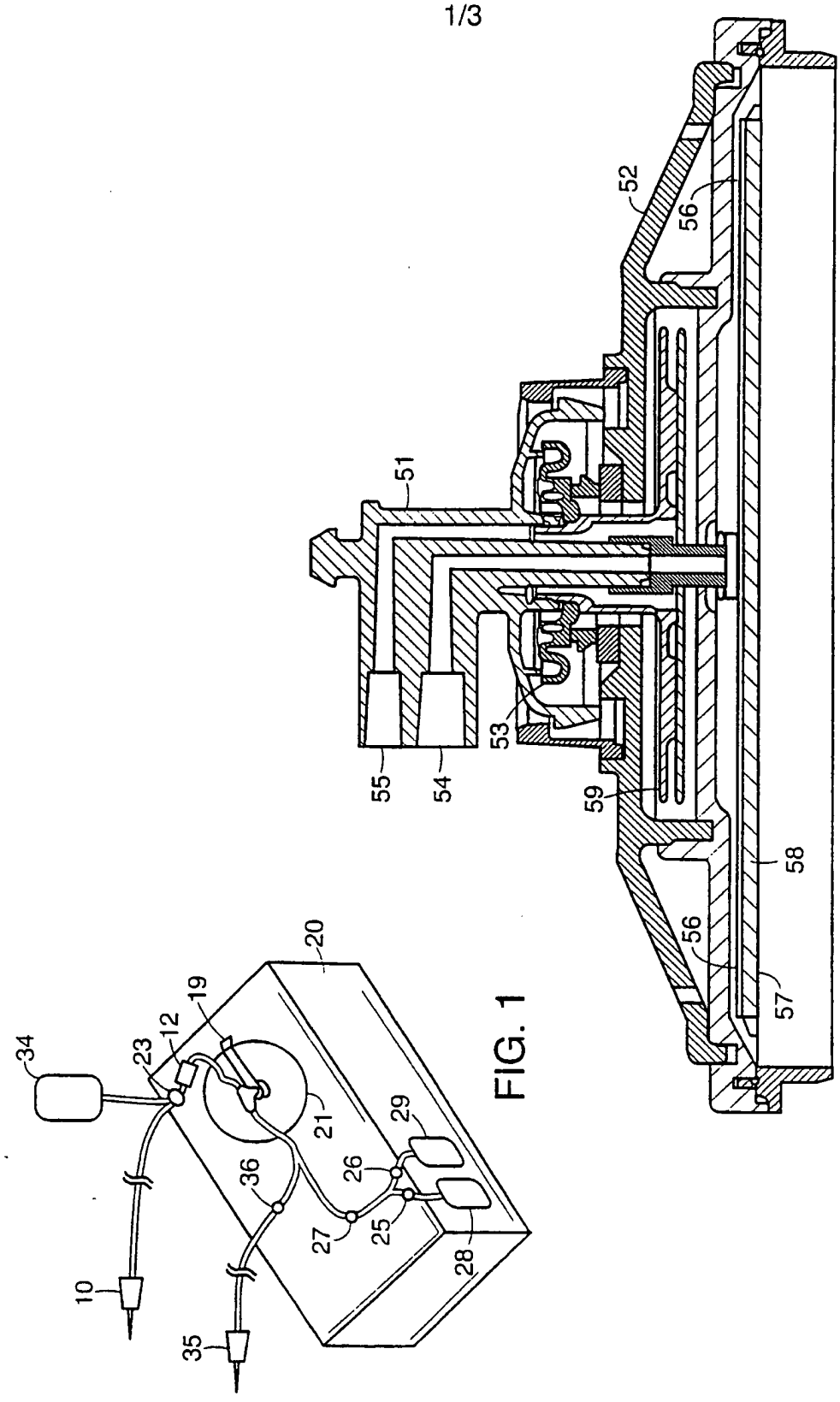


FIG. 1

FIG. 2

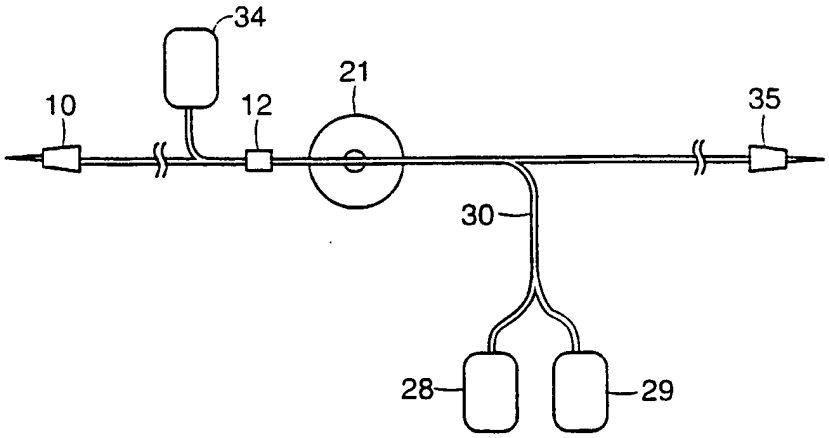


FIG. 3

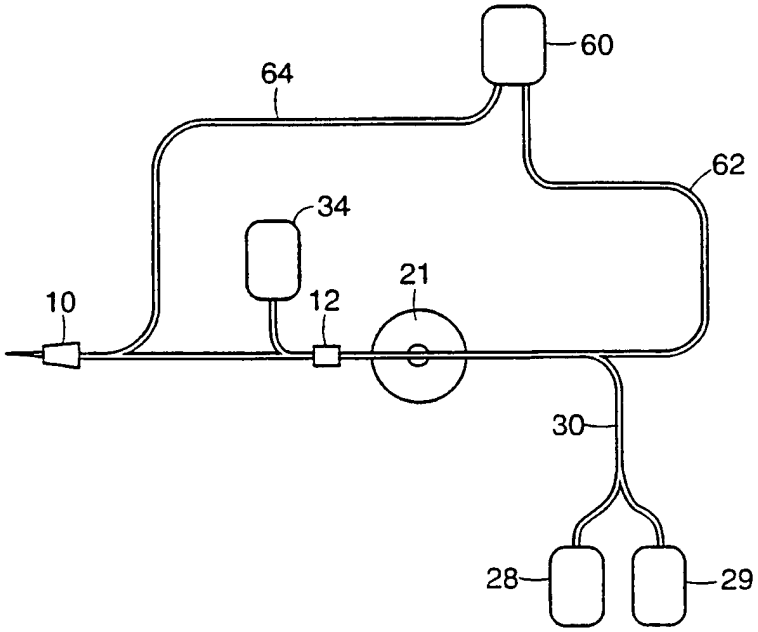
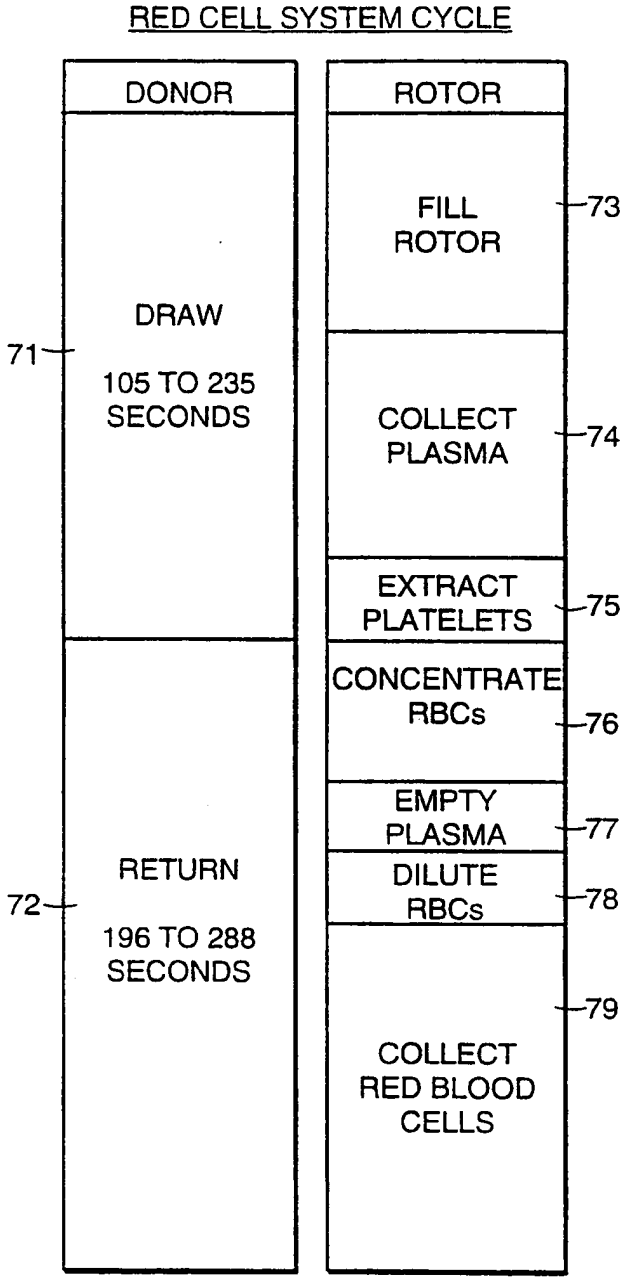


FIG. 4



TOTAL CYCLE TIME: 5 TO 8.7 MINUTES
TOTAL PROCEDURE TIME: 20 TO 34.8 MINUTES

NOTE: TIMES ASSUME HEMATOCRIT RANGE OF 40 TO 55 AND DRAW SPEED RANGE OF 60 TO 100 ML/MIN.

FIG. 5

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/06945

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 733 253 A (POWERS EDWARD T ET AL) 31 March 1998 (1998-03-31) column 18, line 24 -column 19, line 67; claims 45,46	11-24
A	EP 0 349 188 A (ASAHI MEDICAL CO) 3 January 1990 (1990-01-03) abstract; figures	11,13, 16,20
A	EP 0 852 151 A (HAEMONETICS CORP) 8 July 1998 (1998-07-08) abstract; claims 1-3; figure 2	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 2000	14/07/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

information on patent family members

Inter ional Application No
PCT/US 00/06945

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